

REMARKS

Following entry of the amendment as requested herein, Claims 1-4, 14, 16-18, 20, 24-52 are pending in the present application. By present amendment, Claims 5-13, 15, 19, and 21-23 are cancelled without prejudice and Claims 41-52 are newly added claims.

Independent Claim 1 is amended without prejudice to focus the present application on an embodiment of the invention wherein the administering step is drawn to administering a compound of Formula IIb. See, for example, the specification as filed at least at p. 14, lines 1-17 and originally filed Claim 15. This amendment is requested in the interest of advancing prosecution by reducing the number of issues in examination. No admission is made that the claim as previously presented, reciting an art-recognized genus of compounds is not patentable.

Claims 14, 16-18, 20, 24, 34 and 40 are amended and Claims 5-13, 15, 19, and 21-23 are cancelled for consistency with presently amended Claim 1.

Claim 37 is amended without prejudice to focus the present application on an embodiment of the invention including a compound of Formula IIb. See, for example, the specification as filed at least at p. 14, lines 1-17. This amendment is requested in the interest of advancing prosecution by reducing the number of issues in examination. No admission is made that the claim as previously presented, reciting an art-recognized genus of compounds is not patentable.

Claims 38 and 39 are amended for consistency with presently amended Claim 37.

Opportunity has been taken, in amending the claims, to correct typographical errors or to rephrase where it has been desirable to do so for enhanced clarity (*e.g.* Claims 2-4, 14, 30, 33 and 37).

New Claim 41 recites the chronic headache is selected from a group consisting of a muscle contraction headache, a toxic headache, a cluster headache, a traction headache, or an inflammatory headache. Support for Claim 41 is found in the specification as filed at least at p. 4, lines 9-14, p. 5, lines 19-28, p. 6, lines 18-20, and p. 11, lines 11-19.

New Claim 42 recites the compound is administered at a dose of at a maximum 1 g/day. Support for Claim 42 is found in the specification as filed at least at p. 26, lines 23-26.

New Claim 43 recites the compound is administered at a dose of at a maximum 400 mg/day. Support for Claim 43 is found in the specification as filed at least at p. 26, lines 23-26.

New Claim 44 recites a method of suppressing CSD thereby preventing a migraine in a subject by orally administering (R)-2-acetamido-N-benzyl-3-methoxypropionamide. Support for Claim 44 is found in the specification as filed at least at p. 11, lines 21-24 and p. 27, lines 15-18.

New Claim 45 recites orally administering (R)-2-acetamido-N-benzyl-3-methoxypropionamide at a dose of at least about 100 mg/day to a maximum of about 1 g/day. Support for Claim 45 is found in the specification as filed at least at p. 26, lines 20-26.

New Claim 46 recites a method of preventing or treating a headache selected from a group consisting of a muscle contraction headache, a toxic headache, a cluster headache, a traction headache, or an inflammatory headache by administering an oral effective amount of (R)-2-acetamido-N-benzyl-3-methoxypropionamide. Support for Claim 46 is found in the specification as filed at least at p. 11, lines 11-19, p. 26, lines 20-26, and p. 27, lines 15-18.

New Claim 47 recites that the headache is a cluster headache. Support for Claim 47 is found in the specification as filed at least at p. 11, lines 11-19.

New Claim 48 recites administering to the subject a triptan. Support for Claim 48 is found in the specification as filed at least at p. 5, lines 14-17 and p. 6, lines 11-16.

New Claim 49 recites administering to the subject sumatriptan. Support for Claim 49 is found in the specification as filed at least at p. 6, lines 11-16.

New Claim 50 recites the therapeutic combination where the compound of Formula IIb is (R)-2-acetamido-N-benzyl-3-methoxypropionamide. Support for Claim 50 is found in the specification as filed at least at p. 23, lines 10-11.

New Claim 51 recites the therapeutic combination where the further active agent is a triptan. Support for Claim 51 is found in the specification as filed at least at p. 5, lines 14-17 and p. 6, lines 11-16.

New Claim 52 recites a method of suppressing CSD by orally administering about 100 mg/day to about 400 mg/day (R)-2-acetamido-N-benzyl-3-methoxypropionamide. Support for Claim 52 is found in the specification as filed at least at p. 11, lines 21-24 and p. 27, lines

15-18.

No new matter is added and no change of inventorship is believed to result from the amendment of claims as proposed herein.

Applicant reserves the right to reintroduce any cancelled subject matter in one or more later-filed continuation applications.

RESPONSE TO THE OFFICE ACTION DATED 6 NOVEMBER 2009

Restriction requirement

By the present Office Action, Applicant is required under 35 U.S.C. §121 and §372 to restrict the application to one of the following groups:

- Group I: Claims 1-36: a method for preventing or treating a condition associated with CSD with the compounds of Formula IIb; and
- Group II: Claims 37-40: a therapeutic combination having a compound of Formula IIb and a further active agent effective for prevention or treatment of a headache or a CSD-associated disorder.

At the outset, Claim 40 ultimately depends from Claim 1 and should therefore be part of Group I. Applicant provisionally elects with traverse the invention of Group I, embodied in Claims 1-36 and 40 (and new claims 41-49 and 52).

The Office Action (p. 2) states that “[s]ince Groups I-II do not share a special technical feature, there is no unity of invention.” However, both the method and therapeutic combination recite a compound having the Formula IIb.

Finally, in relation to the statement in the present Office Action (p. 2) that the invention “is not a contribution over the prior art (see, e.g. WO 02/15922 [the ‘922 application]...)”, it is noted that the ‘922 application does not teach a method for preventing or treating a condition associated with CSD by administering a compound having the formula IIb or a therapeutic combination having a compound of Formula IIb and a further active agent effective in the prevention or treatment of a headache or a CSD-associated disorder.

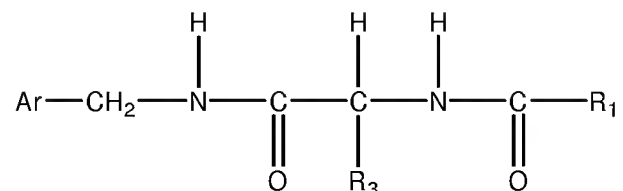
Election of species

By the present Office Action, Applicant is required to elect a single disclosed species

within the provisionally elected Group I.

Applicant provisionally elects with traverse:

- SPM-927 (*i.e.*, the compound of the formula



wherein Ar is unsubstituted phenyl, R₃ is methoxymethyl, and R₁ is methyl); and

- as a species of a CSD-associated condition, chronic headache (Claim 2).

The present election requirement is traversed on the following grounds.

1. The genus of Formula IIb compounds is not so large as to impose an undue search burden on the Office.
2. The genus of CSD-associated conditions, when searched in conjunction with compounds of Formula IIb or SPM-927, does not impose an undue search burden on the Office.

The following claims are readable on the provisionally elected species of Group I: Claims 1-4, 14, 16, 18, 20, 24-36, 40-49, and 52.

The present provisional election of species does not constitute admission that Applicant considers the invention to be limited to such species.

Applicant believes the application is now in condition for examination on the merits. Should any issues remain, the Examiner is invited to call the undersigned at the telephone number given below.